

**Memorandum**

Subject

Meeting with Cardinal Health, Inc.  
Concerning Internet Pharmacies  
DFN: 060-06.05

Date

AUG 23 2005

To

Joseph T. Rannazzisi  
Acting Deputy Assistant Administrator  
Office of Diversion Control

From

Michael R. Mapes, Chief  
E-Commerce Section  
Office of Diversion Control


On August 22, 2005 a meeting was held at DEA HQ between DEA and Cardinal Health to discuss issues related to Internet pharmacies. This meeting was part of a series of meetings being held with controlled substance distributors to discuss their part in preventing the diversion of controlled substances. Michael Mapes and [REDACTED] from OD were present. [REDACTED] from CC was invited but was unable to attend the meeting. Robert Giacalone, Vice President for Regulatory Affairs and Chief Regulatory Counsel and Stephen Reardon, Vice President for Quality and Regulatory Affairs were representing Cardinal Health at the meeting.

We went through a PowerPoint presentation that discussed the Internet pharmacy situation and the role that distributors play in providing controlled substances to Internet pharmacies. Cardinal Health was provided with copies of the presentation as well as copies of each of the laws, policies, and regulations referred to in the presentation. There was much discussion about the characteristics of data that DEA has seen as indicating that the pharmacy could be involved in Internet dispensing of controlled substances.

As an example of distributions by Cardinal Health to pharmacies that are involved in the Internet pharmacy sales, we provided Cardinal Health with a printout that showed their sales to [REDACTED] in Miami, FL. Cardinal Health averaged over 100,000 dosage units of Hydrocodone combination products to [REDACTED] in January, February, and March of 2005. Mr. Reardon advised that they would do some research on that account.

Cardinal Health advised that they will work with DEA to insure that they do not sell to pharmacies who are improperly selling controlled substances. Cardinal requested that DEA provide them with as much information as possible concerning the drugs involved, the states that seem to have more Internet pharmacies than others, and anything else that could help them narrow the scope of their review for suspicious orders.

Attachment: Presentation

ODC:MMapes  :pln:202-353-9562:08/23/05  
Filename: CardinalHealth.doc

PLAINTIFFS TRIAL  
EXHIBIT  
P-09114\_00001

# INTERNET PHARMACY DATA

Meeting With  
Cardinal Health, Inc.  
DEA Headquarters  
August 22, 2005

## Internet Pharmacies

- Domestic Based
  - Related to an existing pharmacy
    - Walk in patients with prescriptions
    - Some legitimate some not
  - Unrelated to brick and mortar pharmacy
    - No local patients or doctors
    - No walk-in business
- Foreign based

## Involved With Internet Pharmacies

- Doctors
- Pharmacies
- Distributors
  
- Internet Service Providers
- Credit Card Companies
- Delivery Services
- Internet Pharmacy Facilitators

## ISSUES TO CONSIDER

- Frequency of Orders
- Size of Orders
- Range of Products Purchased
- Payment Method
- Pharmacy Location
- % Controlled vs. % Non-Controlled
- Customer pick up at distributor

## DEA DISTRIBUTOR REGISTRATIONS

- Title 21 United States Code, Section 823
  - Is the registration in the public interest?
    - Maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical channels

## Supreme Court Case

- Direct Sales Co, Inc. v. United States (1943)
  - Mail order sales to doctor
  - Most sales were Morphine
  - Increase in quantities purchased
  - Business practices attracted customers who were violating the law
  - Drugs have inherent susceptibility to harmful and illegal use

## EZ RX, LLC

- 69 FR 63,178 (2004)
  - Revocation of DEA Registration
  - Immediate Suspension of DEA Registration
    - 300,000 dosage units in three months
    - Phentermine, Phendimetrazine, Ambien

## RX Network of South Florida, LLC

- 69 FR 62,093 (2004)
  - Revocation of DEA Registration
  - Immediate Suspension of DEA Registration
    - 19,300,000 dosage units of various controlled substances
    - Based on Internet Questionnaires
  - Not in the course of professional practice

## Supreme Court Case

- United States v. Moore  
423 U.S. 122 (1975)
  - Usual course of professional practice
    - Patient with a Medical Complaint
    - History
    - Physical Examination
    - Nexus Between Complaint/History/Exam and Drug Prescribed

## DEA Internet Policy

- 66 FR 21,181 (2001)
- Prescriptions can only be issued by a doctor acting in the usual course of professional practice
- Prescription not issued in the usual course of professional practice is not valid
- An Internet questionnaire alone is not sufficient to legally prescribe controlled substances

## VIPPS

- National Association of Boards of Pharmacy
  - Licensed, legitimate, Inspection
  - Verified Internet Pharmacy Practice Sites
  - 14 VIPPS Approved Pharmacies as of 06-27-2005
  - [www.nabp.net/vipps/consumer/faq.asp](http://www.nabp.net/vipps/consumer/faq.asp)

## American Medical Association

- H-120.949 Guidance for Physicians on Internet Prescribing
  - valid patient-physician relationship, includes, but not limited to:
    - History and physical exam
    - Dialogue with patient
    - Follow up to assess outcome
    - Maintain medical record
    - Include electronic prescription in patient's medical record

## Federation of State Medical Boards

- Created Model Guidelines for the Appropriate use of the Internet in Medical Purpose
  - Treatment and consultation made in an online setting will be held to same standard as face-to-face settings.
  - Treatment based solely on an online questionnaire is not acceptable

## Suspicious Orders

- 21 CFR 1301.74
- Requires that registrants design and operate system to identify suspicious orders
- Report suspicious orders to DEA when discovered



## Suspicious Orders

- Reporting a suspicious order to DEA does NOT relieve the distributor of the responsibility to maintain effective controls against diversion

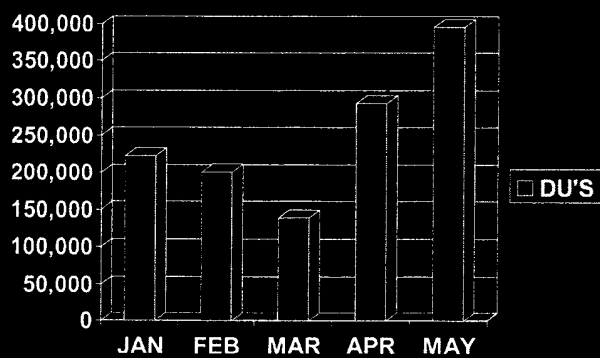
## Suspicious Orders

- DEA cannot tell a distributor if an order is legitimate or not
- Distributor must determine which orders are suspicious and make a sales decision

## Example #1

- Retail pharmacy
  - Quantities of drugs
  - Range of drugs sold – only Phentermine
  - % controlled and % non-controlled
  - Size of orders over time
  - Location of store

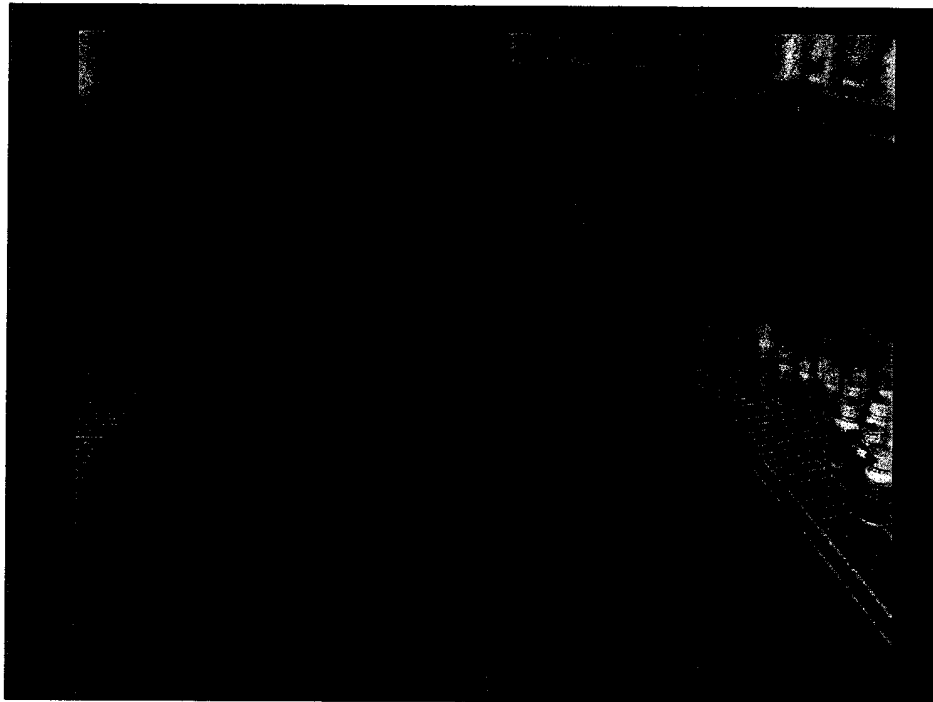
## Example #1



## Example #2

- Retail Pharmacy
  - Location of store
  - Only Hydrocodone and Alprazolam
  - Very large quantities
  - FedEx boxes for delivery

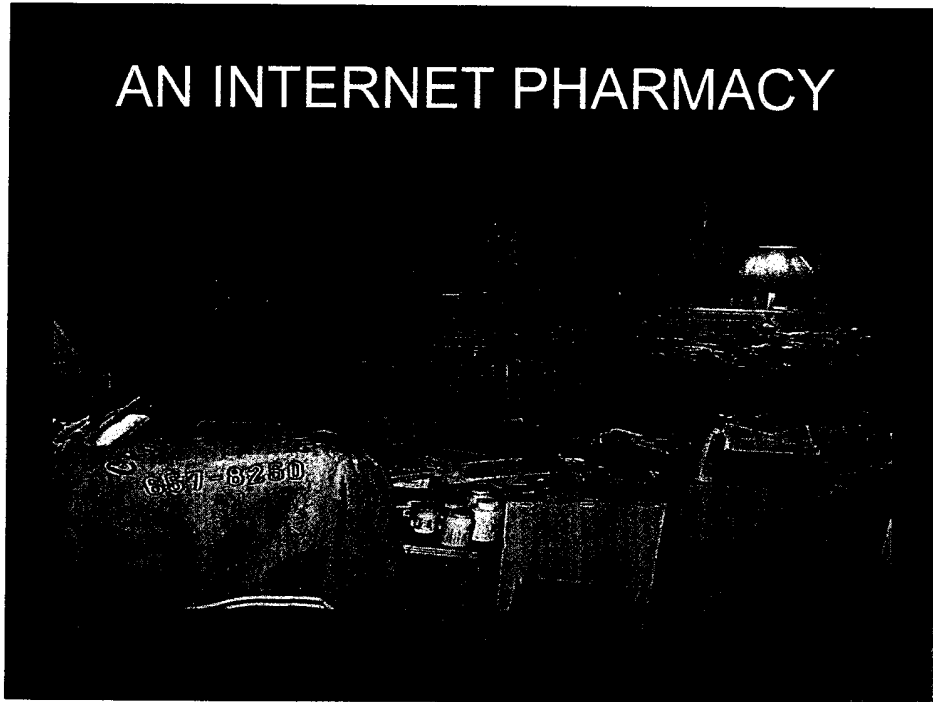
## ANOTHER PHARMACY



### Example #3

- Advised Distributor they are an Internet Pharmacy
- No VIPPS approval
- Frequent Large Orders
- Hydrocodone and Benzodiazepines
- 99% controlled substances
- No established business credit

## AN INTERNET PHARMACY



## SUMMARY

- Prescriptions not written in the usual course of professional practice are not valid
- Drugs dispensed pursuant to invalid prescriptions are not for legitimate medical purpose, the drugs are diverted
- Not limited to Internet pharmacies

## SUMMARY

- A pattern of drugs being distributed to pharmacies who are diverting controlled substances demonstrates the lack of effective controls against diversion by the distributor
- The DEA registration of the distributor could be revoked under public interest grounds

## SUMMARY

- Any Distributor who is selling controlled substances that are being dispensed outside the course of professional practice must stop immediately
- DEA cannot guarantee that past failure to maintain effective controls against diversion will not result in action against a distributor

## SUMMARY

- DEA will:
  - Meet with other distributors involved in distributing to Internet pharmacies
  - Provide this information to your employees at your request
  - Meet with Industry groups or associations to discuss issue if requested

## Contact Information

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Kyle Wright  
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